

3506 (c)(2)(A) of the PRA (44 U.S.C. 3506 (c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility,

and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Petition For Administrative Reconsideration of Action—21 CFR Part 10.33—(OMB Control Number 0910-0192)—Reinstatement

Section 10.33 (21 CFR 10.33), issued under section 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(a)), sets forth the format and procedures by which an interested person may petition the Commissioner of Food and Drugs (the Commissioner) for reconsideration of an agency's action. A petition for reconsideration must contain a full statement in a well-organized format of the factual and legal grounds upon which the petition relies.

The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner. Each petition must be submitted no later than 30 days after the decision involved. The Commissioner may, for good cause, permit a petition to be filed after 30 days. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. FDA uses the information provided to determine whether to grant the petition for reconsideration. Respondents to this collection of information are individuals of households, state or local governments, not-for-profit institutions, and businesses or other for-profit institutions.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN¹

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|----------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 10.33(b) | 7 | 1 | 7 | 100 | 700 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this collection of information is based on agency records and experience over the past 3 years. Agency personnel handling the petitions for administrative reconsideration of an action estimate approximately seven requests being received by the agency annually, each requiring an average of 100 hours preparation time.

Dated: December 10, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0182]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing

that a collection of information entitled "Transmittal of Labels and Circulars, Form FDA 2567" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 19, 1997 (62 FR 49244), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0039. The approval expires on November 30, 2000.

Dated: December 10, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Statement of Organization, Functions, and Delegations of Authority

Part F, of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services, Health Care Financing Administration (HCFA), (49 Federal Register 34247, dated September 6, 1984) is amended to include the following delegation of authority from the Secretary to the Administrator for Title XXI of the Social Security Act.

The specific amendments to Part F are described below:

I. Section F.30., Delegations of Authority is amended by adding the following paragraph: SS. The authority vested in the Secretary under Title XXI of the Security Act (42 U.S.C. 1397aa *et seq.*).

Limitation: No State plan or amendment shall be finally disapproved without consultation and discussion by the Administrator with the Secretary.

II. Section F.30., Delegations of Authority, paragraph RR is revised to include title XXI, the revised paragraph reads as follows: